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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,299	08/20/2004	Jacob Waugh	13720-105110US1	3791

65989 7590 12/26/2008

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EXAMINER	
CARTER, KENDRA D	

ART UNIT	PAPER NUMBER
1617	

NOTIFICATION DATE	DELIVERY MODE
12/26/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomailnyc@kslaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/505,299	WAUGH ET AL.	
	Examiner	Art Unit	
	KENDRA D. CARTER	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44-68,70-76 and 78-85* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *44-68,70-76 and 78-85* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 22, 2008 has been entered.

The Examiner acknowledges the applicant's remarks and arguments of September 22, 2008 made to the office action filed March 20, 2008. Claims 44-68, 70-76 and 78-85 are pending. Claims 44, 56, 68, 76 and 78 are amended.

In light of the amendments, the following rejections are withdrawn: 1) the 35 U.S.C. 112, first paragraph rejection of claims 70 and 78; 2) the 35 U.S.C. 103(a) rejection of claims 44-67 as being unpatentable over Rothbard et al.; 3) the 35 U.S.C. 103(a) rejection of claims 71, 74, 79, 82, 84 and 85 as being unpatentable over Cooke et al. in view of Applicant's admitted prior art, in further view of Fossel; and 4) Rothbard et al. as applied to claims 68, 70, 72, 73, 76, 78, 80 and 81, in further view of Gazzani.

For the reasons in the previous office action and below, the Applicant's arguments of the 35 USC 112, first paragraph rejection of claims 71, 74, 75, 79 and 82-85; 2) were found not persuasive, thus the rejection is upheld.

The Examiner would like to note that claim 82 is incomplete. For compact prosecution, the Examiner has examined the claim based on the previously presented claim language. Corrections are required.

Due to the amendment to the claims and withdrawal of several rejections, the modified and new 35 USC 103(a) and 112, first paragraph rejections are made below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(1) Claims 44-67 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition consisting essentially of a polymer having from 7 to 15 subunits of L-arginine and a dermatologically acceptable vehicle, does not reasonably provide enablement for wherein the

cosmetic formulation does not contain a therapeutic agent that is delivered by the polymer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant claims are drawn to a composition consisting essentially of a polymer having from 7 to 15 subunits of L-arginine and a dermatologically acceptable vehicle. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:
(1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The nature of the invention:

The claim 44 is drawn to a "a cosmetic formulation consisting essentially of (a) a vasodilating amount of a polymer having from 7 to 15 subunits, each subunit consisting of a member of the group selected from L-arginine and physiologically acceptable salts of L-arginine, wherein said polymer increases vasodilation and (b) a cosmetically or

dermatologically acceptable vehicle, wherein the cosmetic formulation does not contain a therapeutic agent that is delivered by the polymer."

(2) The breadth of the claims:

Claims 44-67 embraces and reads on a composition consisting essentially of a L-arginine polymer and a vehicle, wherein the polymer does not deliver a therapeutic agent. Thus, if the claims are read broadly, the polymer can not be a therapeutic agent because the polymer can not contain a therapeutic agent. The specification does not enable the separation of the polymer being a delivery agent and a therapeutic agent.

(3) The state of the prior art:

The state of the art regarding L-arginine polymers being a therapeutic agent and as a delivery device is exemplified by the teachings of Rothbard et al., Fossel and Cooke et al.

Rothbard et al. teaches providing compositions for enhancing the delivery of drugs and other agents across a biological barrier, such as skin, the composition employing a delivery enhancing transporter, such as a poly-arginine molecule that is between 6 and 50 residues in length (see abstract, in particular.) Rothbard teaches that examples of such delivery enhancing transporters can comprise from 7 to 15 amidino moieties, such as heptamers, octamers, nonamers and the like of arginine (see paragraph 0048, in particular.) Rothbard et al. furthermore teaches that the amino acids

can be L amino acids (see paragraph 0055, in particular.) Rothbard et al. teaches that the compositions comprising the polyarginine molecule can comprise a conventional pharmaceutical carrier and can be formulated for topical administration in a suitable format, such as a lotion (see paragraphs 0128 and 0134, in particular), and thus teaches providing a dermatologically acceptable vehicle.

Fossel teaches that a topical (see column 1, lines 1-3) composition comprising L-arginine as the main substance to relax the blood vessels and thus permitting enhancement of blood flow to the tissue (see abstract, lines 1-8), to achieve growth of hair (see column 1, line 10; addresses claims 70 and 78).

Cooke et al. teaches a method of increasing nitric oxide (NO) production in a vascular cell or tissue by contacting a polymer consisting of from 6 to about 30 amino acid subunits such as 7 to 15 L-arginine residues (i.e. Applicant's compound; see column 4, lines 12-18 and claim 26). The arginine oligomers were found to be significantly more efficacious than equivalent amounts of free arginine monomers, which is not significantly taken up by the walls of the arterial and venous segments (see column 10, lines 17-20). The (L)-arginine oligomers enhance NO production by supplementing intracellular (L)-arginine levels (see column 10, lines 26-38).

Thus, L-arginine comprise the property of being a delivery enhancing transporter and enhancing the blood flow to tissue. Therefore, a composition consisting essentially

of an L-arginine polymer will deliver a therapeutic agent, because the polymer is a therapeutic agent.

(4) The predictability or unpredictability of the art:

The predictability of composing a composition of a L-arginine polymer and a vehicle that does not deliver a therapeutic agent is relatively low to impossible. Therefore, to one skilled in the art, prevention of hair loss is highly unpredictable. Particularly, "Products of identical chemical composition can not have mutually exclusive properties." Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F. 2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

(5) The relative skill of those in the art:

The relative skill of those in the art is high, as demonstrated by Rothbard et al., Fossel and Cooke et al.

(6) The amount of direction or guidance presented / working examples:

In the instant case, the guidance of the specification as to a composition consisting essentially of a polymer having from 7 to 15 subunits of L-arginine and a dermatologically acceptable vehicle, wherein the cosmetic formulation does not contain

a therapeutic agent that is delivered by the polymer is completely lacking. The specification teaches that prior art has demonstrated that oligomers of arginine have been shown to provide delivery of other therapeutic agents. In contrast, the present invention is directed to the use of arginine oligomers as prophylatic or therapeutic/cosmetic agents in their own right in treating keratinocyte tissues (see page 5, first paragraph). Thus, the oligomers are taught to have both properties that are not separable.

(7) The quantity of experimentation necessary:

The instant claims read on a composition consisting essentially of a polymer having from 7 to 15 subunits of L-arginine and a dermatologically acceptable vehicle, wherein the cosmetic formulation does not contain a therapeutic agent that is delivered by the polymer. As discussed above the specification fails to provide a composition that can separate the known and presently presented properties of the polymer claimed. Applicant fails to provide any information sufficient to practice the claimed invention, absent undue experimentation. Genetech, 108 F. 3d at 1366 states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimation of general ideas that may or may not be workable.

In conclusion, the applicant is enabled for a composition consisting essentially of a polymer having from 7 to 15 subunits of L-arginine and a dermatologically acceptable

vehicle, but not wherein the cosmetic formulation does not contain a therapeutic agent that is delivered by the polymer.

(2) Claims 74 and 82 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating wrinkles, does not reasonably provide enablement for the stabilization or remodeling of fat. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant claims are drawn to a method of stabilizing or remodeling fat. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:
(1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The nature of the invention:

The claim 74 is drawn to a "method according to claim 68, wherein said cosmetic effect is the stabilization or remodeling of fat."

(2) The breadth of the claims:

Claims 74 and 82 embraces and reads on all conditions that would benefit from the stabilization or remodeling of fat such as weight management or wrinkles. The specification does not enable the treatment of all conditions that would benefit from the stabilization or remodeling of fat.

(3) The state of the prior art:

The state of the art regarding treating all conditions that would benefit from the stabilization or remodeling of fat is very low or do not exist.

(4) The predictability or unpredictability of the art:

The predictability of knowing and then treating all conditions that would benefit from the stabilization or remodeling of fat is low. Therefore, to one skilled in the art, treating all conditions that would benefit from the stabilization or remodeling of fat is highly unpredictable.

(5) The relative skill of those in the art:

The relative skill of those in the art is high.

(6) The amount of direction or guidance presented / working examples:

In the instant case, the guidance of the specification as to treating all conditions that would benefit from the stabilization or remodeling of fat is completely lacking. The specification as filed does not speak on or show any working examples any studies performed that treating all conditions that would benefit from the stabilization or remodeling of fat. The specification teaches that vasodilation may lead to a lesser appearance of certain fine lines and wrinkles (see page 1, last paragraph, last 2 lines). The current specification reaches to all the conditions that exist and those that still have not been determined that relate to the treatment of stabilizing or remodeling fat, with no enablement or prior art for all of these conditions. Note that lack of a working example, is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.02.

(7) The quantity of experimentation necessary:

The instant claims read on the treatment of all conditions that would benefit from the stabilization or remodeling of fat. As discussed above the specification fails to provide any support for treating all conditions that would benefit from the stabilization or remodeling of fat. Applicant fails to provide any information sufficient to practice the claimed invention, absent undue experimentation. Genetech, 108 F. 3d at 1366 states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling

disclosure of an invention, not for vague intimation of general ideas that may or may not be workable.

In conclusion, the applicant is enabled for treating wrinkles, but not for treating the stabilization or remodeling of fat.

(3) Claims 71, 79, 84 and 85 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for alleviating textural discontinuities of the skin, loss of skin firmness, loss of skin tightness and loss of skin recoil, does not reasonably provide enablement for alleviating all signs of aging, particularly discoloration, blotching, sallowness, hyperpigmented skin regions, keratoses, abnormal differentiation, hyperkeratinization, elastosis, collagen breakdown of skin, and histological changes in the stratum corneum, dermis, epidermis, and skin vascular system. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant claims are drawn to a method of alleviating signs of aging in skin such as textural discontinuities of the skin, loss of skin firmness, loss of skin tightness and loss of skin recoil, does not reasonably provide enablement for alleviating discoloration, blotching, sallowness, hyperpigmented skin regions, keratoses, abnormal differentiation, hyperkeratinization, elastosis, collagen breakdown of skin, and histological changes in the stratum corneum, dermis, epidermis, and skin vascular

system. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:
(1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The nature of the invention:

The claim 71 is drawn to a "method according to claim 68, wherein the cosmetic effect is the alleviation of signs of aging in skin." The claim 84 is drawn to a "method according to claim 71, wherein said signs of skin aging are selected from the group consisting of textural discontinuities of the skin, loss of skin firmness, loss of skin tightness and loss of skin recoil, discoloration, blotching, sallowness, hyperpigmented skin regions, keratoses, abnormal differentiation, hyperkeratinization, elastosis, collagen breakdown of skin, and histological changes in the stratum corneum, dermis, epidermis, and skin vascular system."

(2) The breadth of the claims:

Claims 71, 79, 84 and 85 embraces and reads on alleviating all to a large genus of different signs of aging. The specification does not enable alleviation of all signs of aging, or specifically discoloration, blotching, sallowness, hyperpigmented skin regions, keratoses, abnormal differentiation, hyperkeratinization, elastosis, collagen breakdown of skin, and histological changes in the stratum corneum, dermis, epidermis, and skin vascular system.

(3) The state of the prior art:

The state of the art regarding treating all signs of aging or all forms of skin discoloration, blotching, sallowness, hyperpigmented skin regions, keratoses, abnormal differentiation, hyperkeratinization, elastosis, collagen breakdown of skin, and histological changes in the stratum corneum, dermis, epidermis, and skin vascular system is very low or do not exist. Gazzani teaches a composition to treat wrinkles (see abstract). The wrinkles are a result of the blood circulation within the germinative layer being hindered and the feeding of nutrient substances being reduced, which creates an appearance of looking old-looking (see column 1, lines 27-31). Gazzani does not teach that the increase of blood (i.e. such as through vasodilation) to this area would treat all of the signs of aging.

(4) The predictability or unpredictability of the art:

The predictability of alleviating all signs of aging, or all forms of discoloration, blotching, sallowness, hyperpigmented skin regions, keratoses, abnormal differentiation,

hyperkeratinization, elastosis, collagen breakdown of skin, and histological changes in the stratum corneum, dermis, epidermis, and skin vascular system is relatively low. Therefore, to one skilled in the art, alleviation of all or all forms of the above conditions is highly unpredictable.

(5) The relative skill of those in the art:

The relative skill of those in the art is high.

(6) The amount of direction or guidance presented / working examples:

In the instant case, the guidance of the specification as to alleviating all signs of aging, or all forms of discoloration, blotching, sallowness, hyperpigmented skin regions, keratoses, abnormal differentiation, hyperkeratinization, elastosis, collagen breakdown of skin, and histological changes in the stratum corneum, dermis, epidermis, and skin vascular system is completely lacking. The specification as filed does not speak on or show any working examples any studies performed that alleviate all signs of aging or all forms of discoloration, blotching, sallowness, hyperpigmented skin regions, keratoses, abnormal differentiation, hyperkeratinization, elastosis, collagen breakdown of skin, and histological changes in the stratum corneum, dermis, epidermis, and skin vascular system. Note that lack of a working example, is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.02.

(7) The quantity of experimentation necessary:

The instant claims read on alleviating all signs of aging, or all forms of discoloration, blotching, sallowness, hyperpigmented skin regions, keratoses, abnormal differentiation, hyperkeratinization, elastosis, collagen breakdown of skin, and histological changes in the stratum corneum, dermis, epidermis, and skin vascular system. As discussed above the specification fails to provide any support for alleviating all the signs of aging or all the forms discussed above in light of prior art teaching that the increase in blood treats wrinkles (i.e. textural discontinuities of the skin, loss of skin firmness, loss of skin tightness and loss of skin recoil) but not all signs of aging nor those discussed above. One skilled in the art would need to apply the composition to each form of aging to see if it was effective to treat the condition (i.e. epidermis, dermis, blotching). Applicant fails to provide any information sufficient to practice the claimed invention, absent undue experimentation. Genetech, 108 F. 3d at 1366 states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimation of general ideas that may or may not be workable.

In conclusion, the applicant is enabled for alleviating textural discontinuities of the skin, loss of skin firmness, loss of skin tightness and loss of skin recoil, but not for alleviating all signs of aging, particularly discoloration, blotching, sallowness, hyperpigmented skin regions, keratoses, abnormal differentiation, hyperkeratinization,

elastosis, collagen breakdown of skin, and histological changes in the stratum corneum, dermis, epidermis, and skin vascular system.

(4) Claims 75 and 83 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to a method of treating gum regression. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention. Attention is directed to *In re Wands*, 8USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:
(1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The nature of the invention:

The claim 75 is drawn to a "method according to claim 68, wherein the cosmetic effect is the treatment of gum regression."

(2) The breadth of the claims:

Claims 75 and 83 embraces and reads on treating gum regression. The specification does not enable the treatment of gum regression.

(3) The state of the prior art:

The state of the art regarding treating gum regression is medium or high. Chan (US 5,922,756) teaches that excess nitric oxide (i.e. a vasodilator) contributes to chronic inflammation (see column 1, lines 40-43), in which Chan teaches a treatment of chronic and acute inflammatory conditions such as periodontitis by inhibiting nitric oxide synthase (see column 2, lines 20-25 and column 3, line 65). It is known in the art that inflammation leads to gum recession and conditions generically known as periodontal diseases (see Bowen et al.; US 3,952,092; column 1, lines 25-28). Thus, inflammation causes gum recession and gum inflammation is contributed to the excess production of nitric oxide. Therefore, one skilled in the art would not want to provide a vasodilator to treat gum recession.

(4) The predictability or unpredictability of the art:

The predictability of treating gum regression is relatively medium to high. Therefore, to one skilled in the art, treating gum regression is somewhat predictable.

(5) The relative skill of those in the art:

The relative skill of those in the art is high.

(6) The amount of direction or guidance presented / working examples:

In the instant case, the guidance of the specification as to the treating gum regression is completely lacking. The specification as filed does not speak on or show any working examples any studies performed that treats gum regression with the claimed compound by means of dilating blood vessels (i.e. vasodilation) of the gum. The specification teaches that the compositions of the invention "may" reduce the appearance of gum regression (see page 6, paragraph 2, last 2 lines), but no examples showing that the compositions actually treat gum regression in light of prior art teaching that vasodilators cause gum regression. Note that lack of a working example, is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2164.02.

(7) The quantity of experimentation necessary:

The instant claims read on treating gum regression. As discussed above the specification fails to provide any support for treating gum regression. Applicant fails to provide any information sufficient to practice the claimed invention, absent undue experimentation. Genetech, 108 F. 3d at 1366 states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion"

and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimation of general ideas that may or may not be workable.

In conclusion, the applicant is not enabled for treating gum regression.

(5) Claims 70 and 78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Particularly, the independent claims 68 and 76 disclose that the cosmetic effect is not promotion of hair regrowth, whereas the dependent claims 70 and 78 then discloses that the cosmetic effect is promotion of hair regrowth and treatment of hair loss.

(6) Claim 82 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Particularly, after the word "the" on the second line of the claim the cosmetic effect is not disclosed. For compact prosecution, the Examiner has examined the claim based on the previously presented claim language.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

(1) Claims 44-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fossel (US 5,895,658), in view of Cooke et al. (US 6,605,115 B1), in further view of, Rothbard et al (U.S. Patent Application Publication No. 2002/0009491).

Fossel teaches that a topical (see column 1, lines 1-3) composition comprising an effective amount of L-arginine as the main substance to relax the blood vessels and thus permitting enhancement of blood flow to the tissue (see abstract, lines 1-8 and claim 1), to achieve beneficial effects such as warning cold tissue, growth of hair on the scalp, as well as restoration of natural mechanisms based on improvement of local blood supply (see column 1, line 8-14; addresses claims 44, 48 and 60). L-arginine is a precursor to the molecule nitric oxide, NO, being transformed into NO and citruline by the enzyme nitric oxide synthetase. Nitric oxide is the substance that relaxes the blood vessels, allowing for increased blood flow (i.e. vasodialator; see column 2, lines 66-67 to column 3, lines 1-3). L-arginine, in its various forms, may be contained in a variety of topical preparations such as creams (see column 4, line 4 and see column 2, lines 18-20; addresses claims 44 and 61), emulsions, liposomes, collagen peptides, other components of skin (i.e. additional skin care or skin repair/skin barrier repair actives), or

a vehicle such that L-arginine would prefer to be in tissue (i.e. cosmetically or dermatologically acceptable vehicle; see column 3, line 41-44 and 55; 44, 49; addresses claims 50, 53, 54, 62 and 64). In regards to the properties of the components of skin being additional skin care, skin repair or skin barrier repair actives, one can not separate the property from the compound. Increased lipid, oil and/or wax content is encouraged (i.e. natural or synthetic oils; see column 3, line 53; addresses claims 52 and 66). The formulation can further comprise other active agents, such as other agents that can be used which are also precursors or donors of nitric oxide including L-arginine, alkyl esters of L-arginine and salts such as hydrochloride, glutamate, butyrate, and glycolate (see column 3, lines 24-33; addresses claims 51 and 63).

Fossel does not specifically teach the following: 1) a polymer having from 7 to 15 subunits of L-arginine (claims 44-47 and 57-59); 2) the polymer further comprising a hydrophobic, hydrophilic, or amphipathic moiety, or a second polymer, linked or anchored to a terminal L-arginine subunit of the polymer (claims 55 and 67); and 3) the polymer further consisting of one or more additional amino acid other than L-arginine (claim 56).

Regarding claims 44 and 56, it is noted that, for the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, the transitional phrase "consisting essentially of' is being construed as equivalent to "comprising," absent a clear indication

in the specification or claims of what is meant by, i.e. what is being excluded from the composition by, the phrase "consisting essentially of." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355, and MPEP 2111.03. The above applies to all the rejections below.

Cooke et al. teaches a method of increasing nitric oxide (NO) production in a vascular cell or tissue by contacting a polymer consisting of from 6 to about 30 amino acid subunits such as 7 to 15 L-arginine residues (i.e. Applicant's compound; see column 4, lines 12-18 and claim 26; addresses claims 44-47 and 56-59). The arginine oligomers were found to be significantly more efficacious than equivalent amounts of free arginine monomers, which is not significantly taken up by the walls of the arterial and venous segments (see column 10, lines 17-20). The (L)-arginine oligomers enhance NO production by supplementing intracellular (L)-arginine levels (see column 10, lines 26-38).

Rothbard et al. teaches providing compositions for enhancing the delivery of drugs and other agents across a biological barrier, such as skin, the composition employing a delivery enhancing transporter, such as a poly-arginine molecule that is between 6 and 50 residues in length (see abstract, in particular.) Rothbard teaches that examples of such delivery enhancing transporters can comprise from 7 to 15 amidino moieties, such as heptamers, octamers, nonamers and the like of arginine (see

paragraph 0048, in particular.) Rothbard et al. furthermore teaches that the amino acids can be L amino acids (see paragraph 0055, in particular.) Rothbard et al. teaches that the compositions comprising the polyarginine molecule can comprise a conventional pharmaceutical carrier and can be formulated for topical administration in a suitable format, such as a lotion (see paragraphs 0128 and 0134, in particular). Rothbard et al. furthermore teaches that small organic molecule agents can be combined with the transporters to facilitate or enhance transport (see paragraph 0076, in particular.) Rothbard et al. teaches that such compounds can include small organic molecules that have poor solubilities in aqueous liquids (see paragraph 0076, in particular), and thus are hydrophobic.

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the composition and method of Fossel and a polymer having from 7 to 15 subunits of L-arginine (claims 44-47 and 57-59), or consisting of one or more additional amino acid other than L-arginine (claim 56), because of the following teachings: 1) Fossel teaches that the L-arginine agent can be in its various forms (see column 4, line 4), and that the formulation can comprise other agents that can be used which are also precursors or donors of nitric oxide (see column 3, lines 24-33); 2) Cooke et al. teach polymer consisting of from 6 to about 30 amino acid subunits such as 7 to 15 L-arginine residues increase nitric oxide (NO) production in a vascular cell or tissue (see column 4, lines 12-18 and claim 26); 3) Cooke et al. also teach that the arginine oligomers were found to be significantly more efficacious than equivalent

amounts of free arginine monomers, which is not significantly taken up by the walls of the arterial and venous segments (see column 10, lines 17-20); and 4) Cooke et al. teach that the (L)-arginine oligomers enhance NO production by supplementing intracellular (L)-arginine levels (see column 10, lines 26-38). Thus, one skilled in the art would use the oligomers of (L)-arginine with or without other amino acids because they are better vasodiolators than the monomers.

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the composition and method of Fossel in view of Cooke et al. and the polymer further comprising a hydrophobic, hydrophilic, or amphipathic moiety, or a second polymer, linked or anchored to a terminal L-arginine subunit of the polymer (claims 55 and 67) because of the following teachings: 1) Rothbard teaches that 7 to 15 amidino moieties, such as heptamers, octamers, nonamers and the like of arginine provide delivery enhancing transporters properties (see paragraph 0048); 2) Rothbard et al. furthermore teaches that small organic molecule agents can be combined with the transporters to facilitate or enhance transport (see paragraph 0076), which include small organic molecules that have poor solubilities in aqueous liquids (see paragraph 0076), and thus are hydrophobic; 3) the compositions of Fossel are desired to be hydrophobic to enhance delivery (see column 3, lines 39-67). Thus, one skilled in the art would further comprise hydrophobic moieties onto the polymer with expectations of providing a drug that is better delivered through the skin. While Rothbard et al., Fossel, or Cooke et al. do not specifically exemplify

linking the biologically active agent to the side chain of the terminal L-arginine subunit, it is considered that one or ordinary skill in the art at the time the invention was made would have found it obvious to provide such an association, based on the ion pair teachings of Rothbard et al, with the expectation of providing a suitable transport pair for skin treatment.

Regarding independent claim 56, Rothbard et al. furthermore teaches that peptides comprising arginine in addition to other amino acid residues can also be used as the delivery-enhancing polymer, and furthermore teaches that the delivery-enhancing transporters of the invention can be flanked by, or interrupted by, one or even more than one non-guanidino/non-amidino subunits (such as glycine, alanine and cysteine), that do not significantly affect the rate of transmembrane transport of the delivery-enhancing compound compositions (see paragraphs 0048 and 0071, in particular.) Accordingly, Rothbard et al. teaches the polymer having contiguous arginine subunits, with a number of subunits that overlaps with the range claimed in claim 56, the polymer being flanked by one amino acid other than L-arginine, in which the L-arginine subunits would be situated at the C-terminus or the N-terminus of the polymer, as recited in claim 56. Rothbard et al. furthermore teaches providing a dermatologically acceptable carrier in combination with delivery-enhancing polymers, as discussed for claim 44 above, and thus the composition recited in claim 56 is also obvious over the teachings of Rothbard et al.

(2) Claims 68, 70, 76, and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fossel (US 5,895,658), in view of Cooke et al. (US 6,605,115 B1), in further view of Rothbard et al (U.S. Patent Application Publication No. 2002/0009491).

Fossel teaches that a topical (see column 1, lines 1-3) composition comprising an effective amount of L-arginine as the main substance to relax the blood vessels and thus permitting enhancement of blood flow to the tissue (see abstract, lines 1-8 and claim 1), to achieve beneficial effects such as warning cold tissue, growth of hair on the scalp, as well as restoration of natural mechanisms based on improvement of local blood supply (see column 1, lines 8-14; addresses claims 68, 70, 76 and 78). L-arginine is a precursor to the molecule nitric oxide, NO, being transformed into NO and citruline by the enzyme nitric oxide synthetase. Nitric oxide is the substance that relaxes the blood vessels, allowing for increased blood flow (i.e. vasodialator; see column 2, lines 66-67 to column 3, lines 1-3). L-arginine, in its various forms, may be contained in a variety of topical preparations such as creams (see column 4, line 4 and see column 2, lines 18-20). The formulation can further comprise other active agents, such as other agents that can be used which are also precursors or donors of nitric oxide including L-arginine, alkyl esters of L-arginine and salts such as hydrochloride, glutamate, butyrate, and glycolate (see column 3, lines 24-33; addresses claims 68 and 76).

Fossel does not specifically teach the following: 1) identifying a region of the body in need of cosmetic enhancement (claims 68 and 76); 2) a polymer having from 7 to 15 subunits of L-arginine (claims 68 and 76); 3) increase in length or thickness of eyelashes or eyebrows (claims 70 and 78); 4) the polymer further consisting of one or more additional amino acid other than L-arginine , providing that the L-arginine subunits are contiguous and situated at either the C-terminus or the N-terminus of the polymer (claim 76).

Cooke et al. teaches a method of increasing nitric oxide (NO) production in a vascular cell or tissue by contacting a polymer consisting of from 6 to about 30 amino acid subunits such as 7 to 15 L-arginine residues (i.e. Applicant's compound; see column 4, lines 12-18 and claim 26). The arginine oligomers were found to be significantly more efficacious than equivalent amounts of free arginine monomers, which is not significantly taken up by the walls of the arterial and venous segments (see column 10, lines 17-20). The (L)-arginine oligomers enhance NO production by supplementing intracellular (L)-arginine levels (see column 10, lines 26-38).

Rothbard et al. teaches providing compositions for enhancing the delivery of drugs and other agents across a biological barrier, such as skin, the composition employing a delivery enhancing transporter, such as a poly-arginine molecule that is between 6 and 50 residues in length (see abstract, in particular.) Rothbard teaches that examples of such delivery enhancing transporters can comprise from 7 to 15 amidino

moieties, such as heptamers, octamers, nonamers and the like of arginine (see paragraph 0048, in particular.) Rothbard et al. furthermore teaches that the amino acids can be L amino acids (see paragraph 0055, in particular.) Rothbard et al. teaches that the compositions comprising the polyarginine molecule can comprise a conventional pharmaceutical carrier and can be formulated for topical administration in a suitable format, such as a lotion (see paragraphs 0128 and 0134, in particular). Rothbard et al. furthermore teaches that small organic molecule agents can be combined with the transporters to facilitate or enhance transport (see paragraph 0076, in particular.) Rothbard et al. teaches that such compounds can include small organic molecules that have poor solubilities in aqueous liquids (see paragraph 0076, in particular), and thus are hydrophobic.

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the composition and method of Fossel and a polymer having from 7 to 15 subunits of L-arginine (claims 68 and 76), or consisting of one or more additional amino acid other than L-arginine (claim 76), because of the following teachings: 1) Fossel teaches that the L-arginine agent can be in its various forms (see column 4, line 4), and that the formulation can comprise other agents that can be used which are also precursors or donors of nitric oxide (see column 3, lines 24-33); 2) Cooke et al. teach polymer consisting of from 6 to about 30 amino acid subunits such as 7 to 15 L-arginine residues increase nitric oxide (NO) production in a vascular cell or tissue (see column 4, lines 12-18 and claim 26); 3) Cooke et al. also teach that the

arginine oligomers were found to be significantly more efficacious than equivalent amounts of free arginine monomers, which is not significantly taken up by the walls of the arterial and venous segments (see column 10, lines 17-20); and 4) Cooke et al. teach that the (L)-arginine oligomers enhance NO production by supplementing intracellular (L)-arginine levels (see column 10, lines 26-38). Thus, one skilled in the art would use the oligomers of (L)-arginine with or without other amino acids because they are better vasodiolators than the monomers.

Regarding independent claim 76, Rothbard et al. furthermore teaches that peptides comprising arginine in addition to other amino acid residues can also be used as the delivery-enhancing polymer, and furthermore teaches that the delivery-enhancing transporters of the invention can be flanked by, or interrupted by, one or even more than one non-guanidino/non-amidino subunits (such as glycine, alanine and cysteine), that do not significantly affect the rate of transmembrane transport of the delivery-enhancing compound compositions (see paragraphs 0048 and 0071, in particular.) Accordingly, Rothbard et al. teaches the polymer having contiguous arginine subunits, with a number of subunits that overlaps with the range claimed in claims 68 and 76, the polymer being flanked by one amino acid other than L-arginine, in which the L-arginine subunits would be situated at the C-terminus or the N-terminus of the polymer, as recited in claim 76. Thus, one skilled in the art would be motivated to make a derivative of the L-arginine composition of Fossel in view of Cooke with the expectation of providing a vasodilator with enhancing transporter properties.

In regards to identifying a region of the body in need of cosmetic enhancement (claims 68 and 76), Fossel obviously teaches this limitation because Fossel teaches that the composition produces beneficial effects through restoration of natural mechanisms based on improvement of local blood supply (see column 1, lines 11-13). Thus, when one wants to impart the above treatment, one skilled in the art would identify and then apply the composition to the parts of the body that would benefit from restoration of natural mechanisms to provide a therapeutic and/or cosmetic change.

In regards to the cosmetic effect not being a promotion of hair growth, the method provides other beneficial results such as healing leg ulcers, warming cold tissue and other beneficial effects through restoration of natural mechanisms based on improvement of local blood supply (see column 1, lines 11-13).

In regards to increase in length or thickness of eyelashes or eyebrows (claims 70 and 78), one skilled in the art would find it obvious and motivated to apply the composition of Fossel in view of Cooke et al. and Rothbard et al. because Fossel teaches that the composition is effective in growing hair and restoring natural mechanisms based on improvement of local blood supply (see column 1, lines 8-14). Thus, upon increasing the blood flow to the eyelash or eyebrow region, one would increase nutrients that are needed to promote growth of the hair.

(3) Claims 72 and 80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fossel (US 5,895,658), in view of Cooke et al. (US 6,605,115 B1) and Rothbard et al (U.S. Patent Application Publication No. 2002/0009491) as applied to claims 68, 70, 76, and 78 above, in further view of Frome (US 5,571,794 A).

Fossel, Cooke et al. and Rothbard et al. are as applied above to claims 68, 70, 76 and 78.

Fossel, Cooke et al. and Rothbard et al. do not teach the specific cosmetic effects of lip plumpness, change in lip color, or lip contour.

Frome teaches a method to achieve an enlargement of the lips by applying a composition comprising a topical vasodilator (see abstract; column 2, lines 23-46).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Fossel in view of Cooke et al. and Rothbard et al. to provide lip plumpness or contour because Frome teaches that topical application of vasodilators enlarge the lips. Therefore, the topical vasodilator composition of Fossel in view of Cooke et al. and Rothbard et al. would be expected to provide effective lip plumpness due to increased blood flow to the lips.

(4) Claims 71, 74, 79, 82, 84 and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fossel (US 5,895,658), in view of Cooke et al. (US 6,605,115 B1) and Rothbard et al (U.S. Patent Application Publication No. 2002/0009491) as applied to claims 68, 70, 76, and 78 above, in further view of Gazzani (US 5,053,230).

Fossel, Cooke et al. and Rothbard et al. are as applied above to claims 68, 70, 76 and 78.

Fossel, Cooke et al. and Rothbard et al. do not teach wherein the cosmetic effect is that disclosed in claims 71, 74, 79, 82, 84 or 85.

Gazzani teaches that when blood circulation towards and within the germinative layer is hindered, or the feeding of nutrient substances is reduced (which is known that feeding takes place by blood circulation), the layer becomes more and more atrophied and the skin becomes wrinkled and old-looking, while hair follicles lack the capacity for forming new hair (see column 1, lines 25-40).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Fossel in view of Cooke et al. and Rothbard et al. and wherein the cosmetic effect is that disclosed in claims 71, 74, 79, 82, 84 or 85 because of the following teaching: (1) Cooke et al. teach that the

applicant's compound increases the production of nitric oxide; (2) Fossel teaches that a topical composition of L-arginine increases the blood flow to a tissue to achieve growth of hair (see column 1, lines 1-5); and (3) Gazzani teaches that when blood circulation towards and within the germinative layer is hindered, or the feeding of nutrient substances is reduced (which is known that feeding takes place by blood circulation), the layer becomes more and more atrophied and the skin becomes wrinkled and old-looking, while hair follicles lack the capacity for forming new hair (see column 1, lines 25-40). Thus, upon increasing the blood circulation with an L-arginine oligomer to the skin, the tissue area will regain nutrients and blood to reduce wrinkles and the look of old age (i.e signs of aging, loss of skin firmness, loss of skin tightness, loss of skin recoil).

(5) Claims 73 and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fossel (US 5,895,658), in view of Cooke et al. (US 6,605,115 B1) and Rothbard et al (U.S. Patent Application Publication No. 2002/0009491) as applied to claims 68, 70, 76, and 78 above, in further view of Kligman (US 4,877,805 A)

Fossel, Cooke et al. and Rothbard et al. are as applied above to claims 68, 70, 76 and 78.

Fossel, Cooke et al. and Rothbard et al. do not teach wherein the cosmetic effect is to enhance sensitivity to skin.

Kligman teaches that retinoids increase vascularity, which stimulate blood flow and promote the formation of new vessels. Blood flow is greatly reduced in aged, sundamage skin. A brisker blood supply improves the physiologic competence of the skin and imparts a livelier, glowing appearance, in which the patients often say their skin feels "more alive" (i.e. increased sensitivity; see column 5, lines 34-40).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method and composition of Fossel in view of Cooke et al. and Rothbard et al. and a method to enhance skin sensitivity because Kligman teaches that by increasing blood flow through a vasodiolator, the skin is livelier and feels more alive. Further, Fossel teaches that the L-arginine composition warms cold tissue (see column 1, lines 8-14). Thus, upon increasing the blood circulation with an L-arginine oligomer to the skin, one skilled in the art would expect the tissue area to become more sensitive and give the patient a feeling of being more alive.

Response to Arguments

Applicant's arguments filed September 22, 2008 have been fully considered but they are not all persuasive. Applicant's arguments with respect to the withdrawn rejections have been considered but are moot in view of the new ground(s) of rejection.

> The Applicant argues that claims 74 and 82 are directed to a specific type of fat stabilization or remodeling of fat, i.e., fat stabilization or remodeling that is achieved by means of vasodilation. Not "all" conditions that would benefit from the stabilization or remodeling of fat can be achieved with vasodilation.

The Examiner disagrees because even by looking to fat stabilization or remodeling of fat that is achieved by dilating blood vessels, one reaches to all the conditions that exist and those that still have not been determined that relate to the treatment of stabilizing or remodeling fat through dilation of blood vessels. The specification nor does prior art enable all conditions that would benefit from the stabilization or remodeling of fat, in which vasodilation treats. The specification teaches that vasodilation may lead to a lesser appearance of certain fine lines and wrinkles (see page 1, last paragraph, last 2 lines), which can be considered as a remodeling of fat by vasodilation, but by no means does this enable all stabilization or remodeling of fat that can be treated with vasodilation.

> The Applicant argues that the signs of aging in skin which claims 71, 79, 84 and 85 contemplate are those which are treatable by vasodilation, not "all" signs of aging. Moreover, the specific conditions recited in claims 84 and 85 are types of conditions treatable by vasodilation to achieve a cosmetic effect.

The Examiner disagrees because as Gazzani teaches, wrinkles are a result of blood circulation within the germinative layer being hindered and the feeding of nutrient substances being reduced, which creates an appearance of looking old-looking (see column 1, lines 27-31). Gazzani does not teach that the hindrance of blood circulation

causes all the signs of aging disclosed in claims 84 and 85. Further, the independent claims 71 and 79 read on treating all conditions known in the art and those not known in the art that are related to signs of aging that can be treated by vasodilation. The specification nor does prior art enable all "signs of aging" that would benefit from vasodilation.

> The Applicant argues that claims 75 and 83 are not directed to reversing or curing gum regression, which is still thought to be irreversible. Instead, the specification teaches that the appearance of regressed gums can be mitigated by vasodilation for at least a transient cosmetic benefit. To this extent, the present invention is enabled because it is taught in the specification that vasodilation leads to transient, reversible increases in tissue mass and sensitivity. For the same reason, the Chan reference does not teach away from applying a vasodilator to recessed gums. Chan states that "excess NO" can lead to chronic inflammation, in which the claims are not directed to a persistent or excessive application of the claimed composition to the gums, but rather only an effective amount to achieve a transient and reversible cosmetic effect.

The Examiner disagrees because the claim discloses wherein said cosmetic effect is the "treatment of gum regression". Upon one having gum regression, as Chan teaches, the gums are inflamed which is contributed to the excess production of nitric oxide. Thus, the patient already has an excess of nitric oxide upon having gum regression (see column 1, lines 40-43; column 2, lines 20-25; column 3, line 65; also see Bowen et al. US 3,952,092 column 1, lines 25-28). Therefore applying a composition that increases nitric oxide will not treat the gum regression but increase inflammation and thus further gum regression and its appearance.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENDRA D. CARTER whose telephone number is (571)272-9034. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/K. D. C./
Examiner, Art Unit 1617

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617